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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,908	09/18/2003	Dennis M. Godek	PC9940D	8523

28523 7590 11/24/2004

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
EASTERN POINT ROAD
GROTON, CT 06340

EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,908	GODEK ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Macy et al (U.S. Patent No. 5,958,888) or Schadewald et al (U.S. Patent No. ,468,735) in combination with applicant's admittance on page 1 of the specification and Hagan et al (U.S. Patent No. 5,547,964) for the reasons set forth in the Office Action of July 12, 2004 and in further view of Morimoto et al (U.S. Patent No. 4,833,236).

Morimoto et al disclose administration of a macrolide antibiotic at a dosage of from about 1 mg/kg to 50 mg/kg of body weight per day (column 4, lines 43-46), which is within the claimed range which is between about 0.2 mg/kg/day and about 200 mg/kg/day.

Hagan et al disclose administration of Substance P antagonist at a dosage of 0.1 mg/kg to about 400 mg/kg bodyweight per day (column 22, lines 28-40) which is within the claimed range which is between about 2 mg/kg/day and about 7 mg/kg/day.

Applicant's arguments filed October 8, 2004 have been considered but have not been found persuasive.

The macrolide antibiotics are well known to be useful for treating bacterial and protozoa infections and to cause emesis as admitted by applicant on page 1 of the specification. The substance P antagonist is well known for the treatment and prevention of emesis at the dosages which encompass the claimed range as stated above. Therefore, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use Substance P antagonists disclosed by Hagan et al for the treatment of emesis caused by macrolides.

With respect to applicant's argument that the use of compound CP 122,721, a substance P antagonist, completely prevented macrolide-induced vomiting at a dosage of 3 mg/kg but was not effective at a dosage of 1.5 mg/kg, note that none of the claims have been limited to the use of compound CP 122,721 and it cannot be ascertained id many various Substance P antagonists encompassed by the instant claims will be useful at the same dosage. Further, the dosage of "about 2 mg/kg" encompassed by the instant claims reads on the dosage of 1.5 mg/kg, which was found to be not effective. Also, note that Hagan et al teach in column 22, lines 28-39 that "it may be necessary to make routine variations to the dosage, depending on the age and condition of the patient, and the precise dosage will be ultimately at the discretion of the attendant physician or veterinarian. The dosage will also depend on the route of administration and the particular compound selected". Therefore, it would have been within routine experimentation to determine effective dosage of the macrolide antibiotic and substance P antagonist. Also, a compound at a higher dosage would be expected to be more effective than a compound at a lower dosage. Therefore, the claimed methods and compositions are still deemed prima facie obvious over the cited prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

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